

# Intuitive Surgical Devices™ Business Overview

Draft of 10/29/95

Copy Number 26

Issued to Dave Rosa

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**I. Introduction.** Intuitive Surgical Devices™ (the “Company”) is being formed to commercialize a fundamentally new generation of technology for minimally invasive surgery (“MIS”). Major concepts for the technology are being licensed from SRI International (“SRI”), which developed them under approximately \$2 million of grants from the NIH and ARPA. However, all of the Company’s technology is being re-engineered by Intuitive Surgical Devices to meet the needs of commercial endoscopic surgical products.

The Company’s products are designed to make MIS surgical procedures far more intuitive for the surgeon, increasing the surgeon’s confidence on existing procedures and making a broad range of procedures newly suitable for MIS techniques.

The Company will derive its revenues from high margin disposable instruments, as well as high margin “resposable” instruments which can be resterilized and reused only for the number of times allowed by the company. Intuitive Surgical’s instrument system will be:

- More intuitive, capable and flexible than MIS instruments on the market today;
- Manufacturable with high gross margins, and salable at reasonable prices. COGS per procedure is projected to be no higher than existing MIS disposable instruments, even taking into account the amortization of the capital equipment that helps the surgeon control the instruments.

By enabling new procedures to be done in high volume with MIS techniques, and by making existing MIS procedures easier to perform, Intuitive Surgical has the potential for very substantial revenue with high margins. Further, the Company believes that its technology has the potential to break the MIS market out of its current state—of slow product evolution and slow growth of new procedures—into a state of revolutionary product improvements and rapid growth.

While use of the company’s instruments depends on specialized capital equipment designed by the Company, the result of the high gross margins on the Company’s disposable and resposable instruments is that the cost of capital equipment can be made transparent to the customer. The Company anticipates placing its systems in hospitals for little or no up-front charge, in exchange for a disposables purchase contract, in similar fashion to the way clinical chemistry equipment is placed in hospital laboratories in exchange for contracts to purchase reagents. The Company anticipates that one unit of capital equipment with fully burdened COGS of \$50,000-65,000 will generate \$750,000–\$2,000,000 of recurring revenue for the Company over a 5 year period, with 60+% gross margins.

It is also important to realize that unlike many start-up medical device or biopharmaceutical companies, the Company’s products do not require engineering breakthroughs or unknowable interaction with the human body. The engineering required is substantial, but its success is based on the excellent execution of known concepts, as well as on leveraging off of mature engineering technology. Compared with many other medical start-up companies, the interaction of the company’s products with the human body is relatively predictable.

The Company believes that there is significant likelihood that the Company’s products will qualify for 510(k) approval by FDA, rather than the PMA approval process. Even if a PMA

is required, it is anticipated that the number of cases required and follow-up time will be short.

The Company expects to raise \$5 million in its first round financing. Generally, the plan calls for the first product release to be transferred to manufacturing in 24 months. Total cash expenses by the company to reach this milestone are expected to total \$5 million, assuming that equipment is leased instead of purchased, and not including the costs of building a factory and a sales and marketing organization.

**II. Founders.** The Company's is being founded by three experienced entrepreneurial executives from the Silicon Valley medical device industry:

- **John G. Freund, M.D.,** was Executive Vice President of Acuson Corporation and a senior officer there from 1988 through December 1994. Acuson is the leading worldwide manufacturer of medical diagnostic ultrasound systems, with approximately \$350 million in annual sales and 1700 employees. It is traded on the NYSE. Beginning on July 29, 1995, he became a Managing Director in the Alternative Asset Management Group at Chancellor Capital Management; because his involvement in this project began before he began working at Chancellor, his participation does not involve Chancellor.

At Acuson, Dr. Freund was the direct supervisor of the VP—Marketing, and for many years was responsible for the overall cross-functional management of the company's most important product introductions. In that capacity, he developed significant experience in working with Engineering on product specifications and clinical trials; with Marketing and Sales on product positioning, pricing and sales training; and on transfer to Manufacturing. Prior to joining Acuson, he spent six years at Morgan Stanley, from 1982 through 1988. He was a General Partner at Morgan Stanley Venture Partners, responsible for health care investments, and the co-founder of the health care group in Morgan Stanley's Corporate Finance Department. He earned an MBA degree with high distinction from Harvard Business School, an MD from Harvard Medical School, and a BA from Harvard College.

- **Frederic H. Moll, M.D., Medical Director,** was the co-founder of Origin Medsystems in 1988, and served as Origin's Medical Director from the inception of the company through 1994. Origin is a venture capital backed manufacturer of instruments for MIS surgery that was sold to Eli Lilly in 1992 for \$120 million, and is now part of Guidant Corporation, a publicly traded Lilly spinoff. Beginning in 1994, Dr. Moll has served as Medical Director of the business development unit of Guidant.

In 1985, Dr. Moll founded Endotherapeutics, a manufacturer of disposable instruments for laparoscopy, and served as its Medical Director until 1988. Endotherapeutics was acquired by U.S. Surgical Corporation in 1992. Dr. Moll received a B.A. from University of California—Berkeley, an MD from the University of Washington, and an MS in Management from the Stanford Sloan Program. From 1981 through 1984 he was a resident in surgery at the Virginia Mason and University of Washington Hospitals. Dr. Moll is the co-author of



numerous articles regarding new MIS techniques, and holds more than 20 device patents in the field.

- **Robert G. Younge, VP—Engineering**, was the co-founder Acuson Corporation in 1979. He served as Acuson's VP-Engineering from the inception of the company through 1989, when the Company had sales of \$228 million per year and a market capitalization of approximately \$900 million.

In 1991 became the founding General Manager of the Company's Transducer Division, which placed all transducer product development and manufacturing under his common leadership. During his tenure in the transducer division, Acuson introduced its first flexible endoscopic ultrasound transducers and increased yields in transducer manufacturing from 20% to more than 80%, while adding significantly more complex products to its product line.

In addition to being a highly experienced electrical engineer and leader of complex product development and manufacturing organizations, Mr. Younge in the 1970s utilized control systems engineering inventions to develop a new type of plotter for Hewlett Packard, leading to an extremely successful H-P product line of drafting and personal plotters. Mr. Younge received both BSEE and MSEE degrees with honors from Stanford University.

### III. Background on MIS Surgery.

Open surgery, as developed since the advent of general anesthesia, is performed through large incisions in the body. These large incisions allow surgeons to directly visualize and expose tissue for manipulation and excision. As a result, each physical step in conventional surgery is accomplished by natural, intuitive hand movements used to accomplish tasks such as dissection, ligating, and suturing. Surgeons generally prefer open surgical technique to more modern techniques of minimally invasive surgery (described below), because open surgery allows more precise and natural instrument control. However, the disadvantage to the open surgical approach is that the large incisions cause major trauma and result in long and expensive recovery times for the patient.

In the past 15 years, a variety of techniques and associated instruments have been developed that allow surgeons to access the operating field through small punctures ("stab incisions") in the body wall, decreasing trauma, recovery time, and health care costs. Because they avoid the trauma of large incisions, these procedures allow far more rapid patient recovery, with less pain and shorter hospitalization, leading to lower costs. Known as "less invasive", "non-invasive" or "minimally invasive" surgery ("MIS surgery"), these techniques are typically performed using specialized disposable instruments, either under visualization through a fiberoptic scope, or under x-ray visualization via a fluoroscope.

A number of companies who have pioneered MIS techniques have annual sales in the hundreds of millions from MIS instruments. These companies include Ethicon (a subsidiary of Johnson & Johnson), and US Surgical, a public company with sales of perhaps \$500 million from MIS.

Historically, new MIS surgical operations (and the technology that enables them) have been rapidly adopted if the "average" surgeon can learn to perform them with confidence. For example, in the early 1990's, laparoscopic cholecystectomy (removal of the gallbladder)

grew from being a newly-introduced procedure to being almost 100% of cholecystectomies in the US over a 3 year period.

After the rapid growth in laparoscopic cholecystectomy in the early 1990's, many industry analysts predicted that MIS techniques would sweep through most other common surgical operations over the next few years. However, that did not happen, despite the best efforts of companies making MIS devices.

In the Company's opinion, the slow conversion of new operations to MIS techniques has resulted from the difficulty of these new procedures in the hands of the "average" surgeon. The *confidence* of the "average" surgeon is paramount in achieving high penetration for a new procedure. New techniques are not rapidly adopted when only cutting-edge surgeons at academic medical centers can do them, and even then with difficulty: they are rapidly adopted only when a broad range of surgeons at community hospitals can learn to do the new techniques with confidence.

The company believes that during the past 5 years, existing concepts for MIS instruments have undergone only evolutionary improvement. The conversion of new procedures to MIS techniques has reached a state of diminishing returns, determined by the limitations of existing MIS concepts and technology. In order to convert substantial numbers of new operations to MIS, the Company believes that a revolutionary new approach is required. Intuitive Surgical Devices is being formed to commercialize such an approach, which the Company believes will be applicable across a wide range of surgical procedures.

**IV. Limitations of Existing MIS Instruments.** MIS instruments access the body through 2-4 access "ports" created in the body. Ports are typically 5mm or 10mm in diameter and are created by "stab" incisions in the body wall. Through the ports, which are held open by plastic devices called trocars, the surgeon and assistants insert a variety of instruments to manipulate tissue as well as a fiberoptic endoscope through which the operation is visualized on a large television monitor in front of the surgeon.

MIS techniques have been very successful in decreasing patient trauma and length of stay in the hospital. However, surgeons generally find MIS operative technique more difficult to learn and perform than conventional surgery, for reasons that include the following:

- **Non-intuitive Instrument Movements.** Because existing MIS instruments are essentially rigid sticks with a fulcrum where they penetrate the body wall, their "working ends" move in the opposite direction from the hand of the surgeon manipulating the instrument. For example, to move the working end *left*, the surgeon moves his hand to the *right*; to move the working end *up*, he moves his hand *down*.
- **Limited Degrees of Freedom.** Existing MIS instruments offer the surgeon far fewer "degrees of freedom" than a surgeon's hand uses in an open surgical procedure. The rigidity of existing instruments, for example, prevents an instrument from bending around behind tissue, as humans routinely do with their wrists without thinking. As an analogy, surgery with existing MIS instruments is akin to performing open surgery with casts on each arm that prevent movements of the wrist or elbows, and limit movements to those of the fingers or shoulders. The result is that common surgical maneuvers, such as

suturing, can be extremely difficult or impossible to perform with MIS instruments.

- **Poor Sensory Feedback.** In MIS surgery with existing instruments, surgeons cannot directly feel or palpate the tissue, and must depend on the less than optimal "feel" transmitted from the tip of their laparoscopic tools.
- **Non-intuitive Visualization.** The TV monitor that allows surgeons to visualize MIS operations is in front of them and away from the operating site, while the patient is below. This can give the surgeon a feeling of being disconnected from the operating field.

For all of these reasons, existing MIS instruments are significantly less flexible and less intuitive for the surgeon than using open surgical technique.

**V. Intuitive Surgical's Advantage.** The Company's products will use a combination of servo technology, specialized instruments and 3D visualization to make minimally invasive surgery more intuitive for the surgeon to perform, and more flexible with respect to the range of maneuvers the surgeon can confidently carry out. The result will be greater surgeon confidence that will be manifest in three ways, all of which will lower health care costs, speed patient recovery, and increase the utilization of the Company's products:

- (1) **Today's difficult MIS operations will become routine.** Surgical procedures that today are performed only rarely using MIS techniques, in specialized tertiary medical centers, will be performed routinely and with confidence using the Company's products.
- (2) **New Operations will be pioneered.** A number of surgical procedures that today cannot be performed at all using MIS will be made suitable for partial or substantial conversion to MIS techniques.
- (3) **Existing high volume MIS procedures will become easier.** Surgical procedures that today are performed routinely using MIS techniques will be performed more easily and quickly using the Company's technology.

Use of the Company's products will go a long way toward reclaiming for the surgeon the intuitiveness and flexibility of open surgery. By combining many of the natural motions of open surgery with the reduced trauma of MIS surgery, Intuitive Surgical's products will give the surgeon the best of both worlds. It is for this reason that the Company believes that surgeons will use its technology as a platform that will eventually extend into a broad range of operations with very large revenue potential.

Using the Company's products, the surgeon will sit comfortably at a visualization/control station near the operating table. The Company's products will utilize a 3D visualization system that immerses the surgeon in the operating field as if the instruments were extensions of his hands. The surgeon's hands will manipulate control handles that will make him feel much more like he is performing open surgery than MIS surgery. However, these control handles, via servos with tactile feedback, will manipulate right and left laparoscopic arms that cause the actual instruments inside the patient to mimic the physician's hand movements in a natural way. For the first time, a surgeon will move the



working end of an MIS instrument left by moving his hand left; he will move the working end up by moving his hand up.

In short, using Intuitive Surgical's products, the surgeon will perceive that he is looking down into a three dimensional surgical field; he will reach intuitively into the field with his instruments, and operate. Because of coupled servos and force sensors that deliver improved sensory feedback, soft objects will feel soft, and hard objects hard. To the surgeon, this will look and feel much more like conventional open surgery than like current MIS technique. A scrub nurse will stand next to the patient, frequently changing the tools ("end effectors") used inside the patient, such as forceps, scissors, blunt dissectors, etc.

Further, Intuitive Surgical's instruments will allow the instruments to be maneuvered along additional "degrees of freedom" that simply are unavailable or unusable with conventional MIS instruments. Most of the Company's instruments, for example, will include a "wrist" that will allow the surgeon to reach behind and around tissue in an anthropomorphic way (i.e. the movements of the working ends of the instruments will track hand movements made by the surgeon in a way that feels entirely natural). Manipulations like laparoscopic suturing, which today can be only haltingly accomplished by the most dedicated surgeons after many hours of practice (if at all), will be able to be accomplished easily, with little extra training, by a surgeon using the Company's system.

## VI. Intuitive Surgical's Technology.

The Company's technology can be divided into three major components. These will be described in more detail in the section below on Engineering.

**(1) Capital equipment.** The surgeon will sit at a console with a 3D visualization system, and will place his hands into handles that are similar those used in open surgery today. Instrument control arms that extend over the patient will move to exactly track the movement of the surgeon's hands.

Engineering this capital equipment will require considerable mechanical engineering, electrical engineering, and systems integration. However, it will require virtually no software to accomplish movements of the instruments. Instead, board level firmware with no operating system will be used for instrument control, for two major reasons:

- The complex interactions of software and an operating system can lead to unpredictable bugs, which are as unacceptable in an MIS surgery product as they are in the flaps control circuitry of a fly-by-wire airliner. Bugs not found in the software QA process are virtually eliminated by controlling instrument movements using board-level firmware with no operating system.
- Use of firmware eliminates "boot up" time. The Company's capital equipment will be designed to tolerate the fluctuating electrical power often found in hospitals, and will require use of an electrical circuit with emergency back-up generating equipment, which is found in virtually every operating room. However, the short delay between power failure and the start-up of emergency backup power could lead to a system reboot of several minutes if an operating system with software were



used to control instrument movements. This boot-up time is eliminated with the Company's approach.

It is important to understand that the Company's capital equipment is by no stretch of the imagination a robot. Robots have built-in logic that allow them to perform tasks (such as painting the body of an automobile), without contemporaneous human intervention. Instead, the Company's capital equipment is based on servo technology, which simply follows the movements made simultaneously by a surgeon.

Generally, the company's capital equipment will be engineered with redundant systems and conservative design principles to maximize uptime. Careful "mode of failure" analysis will be employed during the architecture and design of the Company's capital equipment so that failures that do occur will be benign, allow fallbacks by the surgeon, and cause no harm to the patient in any failure mode.

It is currently anticipated that the Company's capital equipment will have a cost of goods sold of approximately \$50,000 to \$65,000, fully burdened including factory overhead, warranty reserve, and installation.

**(2) Responsible Transmission Unit.** The capital equipment's instrument control arms above the operating table will move to exactly track the movement of the surgeon's hands. Each of the two arms will attach to an autoclavable Responsible Transmission Unit ("RTU"), which will transmit movements to the disposable end effector and establish the sterile field. In normal operation, a sterile RTU will be attached to each arm at the beginning of an operation and not changed during that operation. At the distal end of the RTU, disposable instruments will be attached; disposables are expected to be changed many times by the scrub nurse during an operation as the surgeon's immediate tasks warrant.

The RTU concept is a proprietary invention of the Company. Its concept is important in development of a system that allows instruments to have more degrees of freedom than existing MIS instruments, while yielding reasonable prices, excellent gross margins, and a business model based on recurring revenue rather than revenue from sale of capital equipment.

The RTU will have characteristics that include the following:

- The RTU will mechanically provide all the degrees of freedom allowed by the Company's surgical instruments except for opening and closing of a clamp, needle holder, or the like (the opening and closing is provided by the disposable, via a linkage in the RTU). As a result, the disposable that attaches to the RTU will be simpler (and cheaper to manufacture) than disposables currently used in MIS surgery: the disposable will have no handle and no stiff elongated shaft, both of which are costly to manufacture in existing MIS disposables.
- Because the RTU has greater degrees of freedom than existing MIS disposables, its manufacturing cost will also be greater. The ability to autoclave the RTU will designed into the product so that its cost can be amortized over several reuses. The number of reuses will be electronically limited as one aspect of the proprietary and patentable interface that will be developed to connect the RTU with the Company's

instrument control arms. The number of reuses will be controlled to reflect the number of autoclave cycles designed into the part, its cost, and the gross margin and price desired. The materials used to construct the RTU will be tailored to combine cost effectiveness, durability for the number of autoclave cycles allowed, and an appearance in keeping with the price as well as the number of autoclave cycles allowed.

- For the purposes of current planning, we assume that a pair of RTUs will have a COGS of \$1000; will sell for \$3000 per pair ASP for 67% gross margins; and will have 15 allowed autoclave cycles. Under these assumptions, the customer will effectively pay \$200 per operation for a pair of RTUs.
- The connection between RTU and capital equipment must be absolutely lockable, so that it cannot inadvertently detach during surgery. When desired, it must be easy for operating room personnel to unlock.
- During the design phase, the company will work closely with its patent attorneys to insure that the interface design between RTU and capital equipment instrument control arms, and between RTU and disposables, have ironclad design patentability. This will secure the Company's responsible and disposable revenue, and insure that other manufacturers will be unable to manufacture unauthorized and possibly dangerous RTUs and disposables.

**(3) Disposables.** The disposables will attach to the distal end of the RTU. As discussed previously, they will be significantly simpler and less expensive to manufacture than existing MIS instruments because most of the cost and complication is designed into the RTU. Gross margin target will be approximately 70-80%. The interface will have characteristics that include the following:

- The connection between RTU and disposables must have two modes. In mode one, the connection is locked, so the disposable cannot detach inside the patient's body. In mode two, the connection must be unlocked so the scrub nurse can easily change disposables many times during the operation.
- As with the interface between RTU and capital equipment described above, during the disposables design phase the company will work closely with its patent attorneys to insure that the interface design between RTU and disposables has ironclad design patentability. This will secure the Company's disposable revenue, and insure that other manufacturers will be unable to manufacture unauthorized and possibly dangerous disposables.

A number of disposables will be designed by the company and will be available for the operations targeted for first product launch. These disposables are listed below in the section called "Procedures Initially Targeted."

Together with the RTUs, disposables are a major part of the recurring revenue the Company will receive from placing its systems. It is expected that systems will be placed

for little or no charge at sites that sign an annual minimum disposables and RTU purchase contract. The minimum contract amount per system is currently assumed to be \$100,000 in purchases per year, which at an average of approximately \$500 per operation translates into approximately 4 operations per week. (It is estimated that a system can handle 3-5 times this at peak capacity).

The relationship between (1) capital equipment cost, (2) resposable cost, price, and number of reuses, and (3) disposables gross margin and revenue, determine the overall gross margin for the company. Costs higher than currently forecast can be covered by increasing the design specification for number of times the RTUs are allowed to be reused. One example of how these parameters translate into gross margin and revenue is presented in the spreadsheet labeled "Gross Margin Model" at the end of this plan. Finally, it is important to note that outside the U.S., medical disposable products are often reused, resulting in very significant revenue loss for the manufacturer. The concept of a resposable with a maximum number of allowed uses will require non-U.S. customers to pay a per procedure charge, at least for the RTUs.

## VII. Procedures Initially Targeted.

The Company believes that the combination of reasonable costs per procedure and greater ease of use will make Intuitive Surgical's products a "platform" technology that surgeons will eventually use for a broad range of procedures. The more the Company can keep revenue per procedure competitive for procedures currently done in high volume using MIS techniques, the more rapidly the technology will drive into the market.

The Company believes that its customers will eventually come to view it as a general purpose system that they use for virtually all MIS procedures, not a special purpose system built for only a few types. However, a focused set of procedures will be initially targeted for promotion at product introduction. These will be targeted at general surgery and OB/GYN, with cardiac surgery to be added as that market develops for MIS procedures but requires more surgeon control and flexibility than is currently being developed by other companies. Procedures will be selected for focus if they have many or all of the following characteristics:

- The procedure is done in high volumes using open surgical techniques, which result in considerable morbidity and relatively long patient recovery times.
- The procedure is one in which only a small percentage of cases is currently being done using MIS techniques, by only a select number of extremely talented surgeons.
- There is something about the procedure that prevents most surgeons from performing it confidently using MIS techniques (e.g. suturing). Whatever the limiting factor is, it must be eliminated or significantly reduced using the Company's products so that many surgeons can now perform the procedure confidently, in high volume.

By targeting these procedures, the Company will insure that the clinical protocol (port locations recommended, end effectors required, etc.) is available at launch to its potential customers. Further, targeting will help the Company enable new procedures to be done in



volume using MIS technique. That "clinical enablement" should help overcome any initial resistance to the product. Once the first customer in a competitive area begins using the system to enable these new procedures, surgeons at other hospitals will have an incentive to adopt the company's products in order to enable them to perform that new procedure and thereby not lose patients to their competitors. Over time, the Company will target additional procedures and will continue to add to its available suite of end effectors.

The reasons for the limitations on current MIS procedures relate directly to the technical and physical constraints in surgical technique which current endoscopic technology imposes. Existing MIS technique necessarily removes the surgeon's hands from the tissue, and instead requires that he operate with long awkward tools that are much more difficult to control and provide less depth perception, tactile feedback, or delicate dissecting or suturing capability. Because of these limitations in current MIS instrumentation, MIS surgery has, to date, has been limited to procedures which require only gross motor movements, and no need for accurate suturing or fine tissue dissection. Further, MIS surgery typically takes significantly more operating room time (which is extremely expensive) than the open surgery it replaces.

As a result, the procedures initially targeted will typically be enabled by provision of the ability to suture or dissect fine tissue by the Company's products.

The Company's technology will offer to the surgeon the ability to regain many of the fine motor movements lost in conversion to current MIS techniques. The Intuitive Surgical system will enable the surgeon to once again perform delicate maneuvers such as suturing, dissection and tissue retraction, techniques that are fundamental to advanced surgical procedures. Reduction in operating room time may also result from the more intuitive nature of the Company's products, although this reduction is less certain.

A spreadsheet that sets forth market projections about the procedures initially targeted is attached as Exhibit A. A verbal description of why Intuitive Surgical's products are likely to enable the targeted procedures also follows here.

#### **A. GENERAL SURGERY**

- **Nissen Fundoplication.** Nissen Fundoplication is another common general surgical procedure, which is performed to correct esophageal reflux. An elective procedure, it is currently performed on only a small fraction of candidates because of its extremely long recovery time. The Company believes that the widespread use of MIS techniques would substantially increase the number of Nissen procedures performed every year.

Currently, there are only a limited number of general surgeons that are skilled in the procedure of laparoscopic Nissen fundoplication. The Company's technology will significantly improve the ease of performing this operation. It will thereby drive adoption of the MIS approach into the hands of a broader number of surgeons; further, the widespread availability of the MIS approach will greatly expand the number of cases performed for this elective procedure.

Specifically, Intuitive's technology will address the two most difficult procedural steps in this procedure: (1) esophageal dissection, and (2) suturing of the fundus. The most dangerous step in any Nissen



procedure involves the careful exposure and dissection of the posterior attachments of the esophagus to underlying tissue. In the process of dissection, there is always significant risk of inadvertently (and often unknowingly) damaging esophageal anatomy, causing perforation of the organ. Esophageal perforation is an extremely morbid and often fatal complication of fundoplication and, when it happens in MIS procedures, is frequently the result of the inability of conventional laparoscopic dissection instruments to follow the curvature of the posterior esophageal surface. By delivering to the surgeon the ability to intuitively curve an instrument around a non-linear surface, the Company's technology will dramatically reduce the chance of traumatic perforation in this procedure. As importantly, easier manipulation of instruments afforded by the system will make the process of fundal suturing (the process of wrapping the stomach around the esophagus and securing it in place) easy to perform for surgeons who have had no advanced laparoscopic training.

With the widespread adoption of the Company's products, it is believed that the number of Nissen procedures done and the number of surgeons able to do a Nissen using MIS techniques would be greatly expanded.

- **Colon Resection.** Removal of the colon or large bowel is a common general surgical procedure done for both benign and malignant disease. Colectomies are accomplished in a variety of ways by removing all or part of the colon (hemi- or total colectomy). These are complicated procedures and involve resecting a portion of diseased tissue and then reanastomosing the two ends of the colon to reestablish continuity of intestinal flow. The challenge in the minimally invasive technique is to have enough manipulating capability to perform fine dissection of the colon from its peritoneal attachment, and then be able to sew or staple the ends of the bowel to accomplish the reanastomosis. The procedure is currently done by only a small fraction of general surgeons. By making dissection much more intuitive, the Company's products will provide for a much more general acceptance of the MIS alternative.
- **Cholecystectomy.** Cholecystectomy refers to the removal of the gall bladder and involves the complete removal of the organ with ligation of its blood supply (cystic artery) and tubular connection to the biliary system (cystic duct). Cholecystectomy is the most common procedure performed by general surgeons and has been recently transformed from open surgery to a laparoscopic technique. Although the laparoscopic technique is now very well accepted and has become a standard of care in removal of the gall bladder, there are specific aspects the technique that can be dramatically improved by use of the Company's products. The standard open cholecystectomy procedure involves a delicate dissection of two important structures—the cystic artery and cystic duct. In the laparoscopic alternative, there continues to be a risk of injuring the common bile duct, a vital structure which lies adjacent to the cystic duct. This risk exists despite continued refinement of the technique of laparoscopic cholecystectomy and relates directly to the lack of precise dissection and palpation capability with current laparoscopic instruments. Use of the Company's products will greatly increase the surgeon's ability to manipulate and dissect tissue and

therefore decrease the chances of injury to the common bile duct as well as increase the speed at which the procedure can be accomplished.

- **Hernia Repair.** Repair of inguinal hernias is the second most common procedure done in general surgery. A hernia is caused by a defect or weakness in the inguinal fascia in the pelvic region of both males and females. There are a variety of hernia procedures in both open and laparoscopic technique. However, in the minimally invasive approach, the lack of precise dissection capability inhibits adoption of the laparoscopic alternative. Specifically, the delicate dissection of the spermatic cord structures and the peritoneal sac, which is oftentimes adherent to the inguinal anatomy, is very difficult for surgeons to learn using MIS techniques. Introduction of the Company's products will drive procedures to the minimally invasive approach by removing the training barrier that limits adoption.

## **B. GYNECOLOGY**

- **Infertility.** Laparoscopy has been used for two decades in a large number of diagnostic infertility procedures in gynecology. However, MIS therapeutic techniques have been much slower to develop. Although there are a variety of infertility procedures which can currently be performed by a few gynecologists using MIS techniques, these procedures are relatively difficult to perform using conventional laparoscopic tools, because of the lack of tissue control, reduced ability for fine dissection, and lack of suturing capability. The introduction of the Company's products will open to all gynecologists the ability to do sophisticated procedures such as tubal reanastomosis and dissection of ovarian cysts, as well as common procedures such as oophorectomy and salpingectomy.
- **Hysterectomy.** Hysterectomy is one of the most commonly performed surgeries in gynecology and involves removal of the uterus. It can be done by open or laparoscopic techniques. Like colon resection, it demands a significant degree of tissue manipulation in the dissection and ligation of blood vessels, ligaments and other pelvic structures. Further, laparoscopic techniques used in this procedure increase the risk of injury to the ureters, vital structures that provide the conduit between the kidney and bladder. It is often difficult to ensure the identification and prevention of injury to the ureters and bladder with conventional laparoscopic instruments because of the limited angles at which these instruments can be positioned. The Company's products will greatly increase the surgeon's dexterity in this procedure and, as a result, have a significant impact on safety, operating time, and rate of adoption of MIS techniques in hysterectomy.
- **Bladder Neck Suspension.** Bladder incontinence is a widespread condition affecting middle aged women, which can be treated surgically with a procedure known as bladder neck suspension. This procedure involves the elevation of the bladder neck by suspension with sutures, surgically recreating the normal angle of the urethra and reestablishing bladder sphincter control. The procedure works well in open surgery

and is the “gold standard” for correction of bladder incontinence. However, because of its long recovery time, most women who would be candidates are discouraged from undergoing the procedure using open technique. Instead, they use adult diapers for their incontinence—an embarrassment and inconvenience. Bladder neck suspension can currently be done laparoscopically but is difficult to perform because of the need to suture at awkward angles using conventional laparoscopic tools. The Company’s products can provide an ideal solution for suturing the bladder neck and would represent a significant advance in incontinence surgery.

### **C. CARDIAC SURGERY**

There is currently significant interest and activity in both the surgical and business community in accomplishing the transition of coronary artery bypass grafting (CABG) and cardiac valve replacement (valve surgery) from open surgery to MIS techniques.

Although this transition has barely begun, a fundamental barrier to the ultimate success of any truly minimally invasive CABG or valve replacement procedure appears to exist, both today and in the foreseeable future. This barrier—one that the Company believes it will be uniquely positioned to address—is that the microsuturing of cardiac structures (e.g. heart valves or coronary vessels) is extremely difficult to do even in an open procedure, and is therefore doubly difficult to accomplish via an endoscopic technique.

In the process of bypassing coronary arteries or replacing valves, both by open surgery and by MIS, the surgeon must both delicately dissect and then suture very small structures under significant magnification. This tedious process is made exceedingly difficult when one attempts to replicate the necessarily delicate surgical movements in an endoscopic format. Because the coronary arteries are so small, especially in their distal portion, this suturing is even more difficult for CABG than for valve replacement; many surgeons (for example, non-cardiac surgeons) do not have the manual dexterity to perform small CABG suturing even using open surgery.

By offering a means for much more precise, intuitive instrument manipulation, the Company’s technology will fundamentally enable these procedures to be accomplished using MIS. Thus, the Company expects the application of its technology to cardiac surgery to eventually develop into an exceedingly valuable and highly visible portion of its product offering.

### **D. OTHER SURGICAL PROCEDURES AND SPECIALTIES**

The company’s products may make a significant difference to many other types of procedures in General Surgery and in OB/GYN, as well as in other specialties. Targeting procedures in other specialties is assumed to be deferred to the future, however, simply because of the desire to target a “critical mass” of procedures in General Surgery, OB/GYN and possibly Cardiac Surgery, which seem most appropriate as targets for the company’s initial product releases.



**E. END-EFFECTORS REQUIRED FOR FIRST PRODUCT LAUNCH.** Examples of the “end effectors” required to be available at first product launch, for various operations, is as follows. Obviously, this list will be refined as specific procedures are targeted and move through clinical evaluation:

- Kittner
- Curved dissector with cautery
- Straight dissecting graspers with cautery.
- 5mm clip device
- Needle driver
- Suction/irrigation device
- Babcock

The Company believes that the procedures targeted for first product launch will be sufficient to eventually produce revenue in the hundreds of millions of dollars. In addition, after the first product launch, the Company will continuously add new end effectors to its product line that will work with its installed base of capital equipment. Intuitive Surgical’s growing reputation and enlarging catalog of end effectors, together with work with luminaries to identify new access ports and surgical methods for existing and new procedures, will continuously increase penetration of the Company’s products.

### **VIII. Sales and Marketing.**

Details on a sales and marketing plan will be left to a future business plan. However, the Company believes that the impact of its technology will be significant enough to justify a direct sales and applications force in the United States and in major Western European countries. The Company currently assumes that it will use distributors in other countries.

During development, the Company will work closely with MIS surgical luminaries to determine the ports, methods, and end effectors required to make Intuitive Surgical’s products optimal for rapid adoption by the market. It is expected that luminaries will write and present papers describing the methodology used for various operations they help perfect, and in some cases will organize seminars that may be sponsored by the Company.

The Company will use its sales organization, trade shows, luminaries and PR to promote its products, and will use luminaries and its applications force to train surgeons on the use of its systems. In the first few years after the Company introduces its products, it will use PR agencies to help its customers promote, on a local basis, the availability of an advanced new system that enables specific types of operations to be performed less invasively. The Company believes that by their nature its systems will receive considerable media attention, especially as its products enable the broad adoption of MIS operations that are of high interest to the public, such as bladder neck suspension.

**IX. Competition.** To the company’s knowledge, no one is currently working on an approach similar to SRIs or the Company’s. An incomplete review of major competitors in



the MIS field, as well as technology believed to be under development from smaller companies that might be construed to be somewhat similar, is reviewed below.

**U. S. Surgical.** The market for MIS instruments and supplies is dominated by two companies which together enjoy an approximate 90% market share. United States Surgical Corp. (Norwalk, Connecticut) was the leader in the development of modern MIS instrumentation, and manufactures premium priced disposables for procedures in general surgery, gynecology and urology. With revenues just over \$1 billion, USSC is considered the leader in the MIS market. However, due to rapid overexpansion and volatile quarterly results, followed by significant financial distress, USSC's market position and market share has slipped significantly in the last 48 months. The company appears to be in a phase of restructuring and is not expected to consider technologic approaches similar to Intuitive Surgical's because the technology is outside U.S. Surgical's exclusive focus on hand held disposable instruments.

**Ethicon.** The Ethicon division of Johnson & Johnson is the second major competitor in MIS. Ethicon's revenues in the Endosurgery division are similar to U.S. Surgical, with each company controlling approximately a 45% market share. Historically, Ethicon has positioned itself as a "fast follower" in the MIS disposable market, and has recently become very successful in taking market share away from U.S. Surgical through product line extensions and heavy marketing. Ethicon is not expected to begin development of a system similar to the Company's because of their lack of expertise in capital equipment, and the corporate "wait-and-see" approach.

**Jet Propulsion Laboratory.** The Jet Propulsion Laboratory of NASA, under the direction of Dr. Steve Charles, is developing a robotic system capable of making minute, precise incisions for use in MIS eye surgery. Dr. Charles, an Atlanta based ophthalmologist, is leading the effort in an attempt to bring microcutting into the field of microsurgery. Because all surgeons' hand movements have a natural tremor which is magnified in microsurgery, robotics can play a role in bringing more precise technique to ocular procedures. However, the system which JPL is developing has neither the capability of simulating normal surgical movement, nor delivering the types of tools necessary to accomplish most surgeries outside of ophthalmology.

**Computer Motion.** Computer Motion, Inc., based in Santa Barbara, California, has developed a system of holding and positioning a visualization endoscope without human assistance for a variety of laparoscopic procedures. It is more a robot than a servo, and was designed by robotics engineers. More importantly, although manipulation of the visualization system is one component of the tasks that a surgeon must accomplish in performing MIS surgery, Computer Motion currently makes no attempt to deliver the end effector capabilities that Intuitive Surgical will be designing to enable new or better MIS procedures. It is believed that Computer Motion is underfunded and will therefore concentrate on robotic movement of visualization systems.

**IBM.** The Thomas J. Watson Research Center at IBM has for a number of years been involved a project to develop a robotic assistant for laparoscopic surgery. The focus of the project is apparently to develop "intelligent" surgical systems that can off-load tasks from a surgeon and reduce the number of people in the operating room. The project seems to be based on a robotic approach, not a servo approach; the goal is to develop a system "capable of operating both under the surgeon's

direct control and more autonomously under a surgeon's supervision while extracting targeting information from realtime images." It is believed that this project has now been discontinued by IBM.

## **X. Engineering.**

**Overview.** Generally, the plan calls for the first product release to be transferred to manufacturing in 24 months. The engineering staff is planned to number 13, as follows:

VP Engineering	1
Mechanical engineers	4
Mechanical packaging designer/industrial designer	1
Servo Engineer/software	1
Hardware designer (EE)/systems	1
Manufacturing engineer	1
Regulatory/safety engineer (EE)	1
Techs	2
Support	1

The emphasis in Engineering will be on hiring a small, cohesive team of first class engineers. It is critical to architect the capital equipment and RTUs for "clinical robustness", a term which we use to connote a number of things:

- The capital equipment in the first product release must handle a wider range of motions than anticipated for the first procedures targeted, to allow for unanticipated movements that a surgeon may wish to do and considerable latitude to perform procedures that were not initially targeted.
- The capital equipment in the first product release must have "hooks" for extra degrees of freedom. Thus, should additional degrees of freedom or wider ranges of motion be required or desired in subsequent releases, they can be added without completely re-engineering the capital equipment. Modifications to the capital equipment should be field upgradeable to the installed base for a number of releases. It will be important to work with the Chief Medical Officer and luminaries to anticipate future uses as much as possible.

During the development phase for the first product, it is critical for Engineering personnel to work closely with surgical luminaries. Clinical robustness can only be built into a product when the engineering team has fully internalized the applications that the product will be used for, and understands how the customer thinks. Intuitive Surgical's products will succeed because their industrial design and ergonomics make them easy and pleasurable to use.

The luminaries must be chosen not only for their expertise in particular operations that are of interest to the Company, but also for their ability to anticipate how drawings and written specifications will eventually translate into products usable by both luminaries and community surgeons—a rare skill.

It will be the responsibility of the Engineering team to finalize all specifications, after internalizing all necessary input from luminaries, marketing staff, and the Chief Medical Officer. Since engineers will be spending considerable time watching human and animal

surgical procedures, finding luminaries in the Bay Area will greatly increase engineering efficiency and keep travel costs down.

Four appendixes at the back of this plan give more detail on the Engineering plan:

- A block diagram and detailed description of the system is attached as Appendix A
- A breakdown of projected fully-burdened COGS for manufactured capital equipment is attached as Appendix B.
- A schedule for Engineering and prototype development is attached as Appendix C.
- A detailed description of objectives for the Engineering development phases is attached as Appendix D.

**XI. FDA Issues.** At present, the Company has not submitted any designs to FDA, or had any preliminary meetings with the agency. Thus, the regulatory requirements for the system to gain approval for sale in the US are unknown. Two possible paths exist for approval of the Company's technology—a 510(k) route, or the lengthier PMA route. Although it is impossible to predict which path will be required, there is some evidence that the shorter and less costly 510(k) route is a likely option. First, the initial procedures targeted by the Company in General Surgery and OB/GYN are relatively low risk with regard to the possibility for patient injury, and thus the FDA is expected to impose less rigid safety and efficacy requirements than for procedures such as Cardiac Surgery. Second, through the product offering of at least two other surgical device companies, Computer Motion and Origin Medsystems, there exist what are called "predicate devices" which provide examples of devices that may be considered equivalent to the Company's and therefore would support and legitimize a 510(k) filing. Finally, the Company currently intends to claim that its products are general purpose, to be used by the surgeon for procedures as he or she sees fit. The Company believes that claims for safety and efficacy of its technology for specific procedures would more likely subject it to the need for PMA clearance.

Intuitive Surgical's founders recently consulted with an attorney who represents medical companies on FDA matters, who concluded that, while there were no guarantees, there was a strong possibility that FDA would allow the company to use a 510(k) method of clearance.

To the extent that a PMA is required, the Company believes it would not be a lengthy one. FDA-required follow-up for the general surgery and gynecology procedures targeted is likely to be short, and the Company expects, in a small number of clinical cases, to be able to demonstrate the generalized ability to faithfully and intuitively track the surgeon's hand movements—an ability that can later be generalized by the medical community to other procedures.



## **XII. Relationship with SRI.**

Dr. Freund currently has an Option Agreement with SRI (assignable to Intuitive Surgical) to acquire worldwide exclusive rights to SRI's intellectual property for its "Telepresence Surgical Technology" project. Coincident with the receipt of its first round funding, the Company will execute a license with SRI to acquire all SRI technology, for the surgical field of use, that relates to the Telepresence Surgical Technology project. Other important terms of the license are as follows:

- The license will be exclusive, worldwide and royalty free, for the life of the last to expire patent. SRI will receive 7.5% of the fully diluted equity equivalents of the Company at the time the first \$5 million has been invested in the company; after then, SRI will receive no additional stock.
- The Company will prosecute any patent filings regarding the licensed technology once it executes the license.
- SRI will retain the rights to its technology outside the surgical field of use.
- During a period ending September 1997, any enhancements that SRI develops to its technology will be licensed to the company, worldwide and royalty free, in the surgical field of use. During the same period, for purposes outside the surgical field of use, the Company will grant a royalty free license to SRI for any intellectual property the Company develops.
- The company will reimburse SRI for \$116,000 it had spent in patent prosecution and filing expenses on this project through September 1995, additional patent expenses SRI makes with the prior approval of the Company between September 1995 and the execution of a License, and up to \$10,000 in SRI's potential costs for outside attorneys to negotiate terms of the License.

## **XIII. Patent Issues and Intellectual Property.**

- SRI has made two US patent applications regarding its technology, covering numerous claims. Both patents were initially rejected by the U.S. Patent Office, and SRI is currently appealing them and amending claims. There can be no assurance that any claims will be granted under any of these filings.
- As discussed above, the Company believes that it will be successful in engineering patentable interconnections between its capital equipment, RTU, and disposables. It also believes that other significant patents may derive from its commercialization of the products described herein.
- To the best of Company's knowledge, development and marketing of the capital equipment and RTU products described herein will not infringe others' patents, or others' patents can be designed around. Development of some of the end effectors desired after the ones targeted for first product release may require licenses for patents owned by other companies. There can be no assurance that



licenses to other companies' patents will be granted at all, or that the terms of any proposed license will acceptable to the Company.

**XIV. Projections.** A full set of financial projections is beyond the scope of this business plan. The following Exhibits are attached to this plan, however:

**"High Volume Surgical Procedures"**, a spreadsheet which gives approximate figures for the number of annual procedures of the types that the Company proposes to target; a projection of the approximate maximum adoption rates of the Company's technology for each for these surgical procedures; and a projection of the recurring revenue (disposables + RTUs) that the Company expects for each of these procedures. Please note that the Company expects that its technology will also be adopted for a broad range of other procedures that are difficult to quantify, and are therefore not estimated in this spreadsheet.

**"Annual Revenues"**, a spreadsheet which estimates total revenue for the Company in the first 5 years of sales. The revenue numbers are based on the procedures in the previous spreadsheet, together with assumptions on the percentage of the maximum adoption rate that the Company can achieve for any given year.

**"Gross Margin Model"**, which shows the relationship between price, COGS and gross margins for the Company's capital equipment, RTUs and disposables, depending on certain assumptions.

**"Engineering Expenses,"** which projects Engineering expenses for the two years that the Company believes will be required to complete development and complete engineering transfer of its capital equipment, RTU design, and initial disposables to manufacturing.

**"Total Expenses,"** which projects all Company expenses for the same two year period.

**XV. Advisors/Experts.**

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